IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

IN RE NAMENDA DIRECT PURCHASER ANTITRUST LITIGATION

Case No. 1:15-cv-07488-CM (RWL)

MEMORANDUM IN SUPPORT OF FOREST'S MOTION *IN LIMINE* 9 TO PRECLUDE EVIDENCE OF SPECULATIVE LESS RESTRICTIVE ALTERNATIVES

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Philip Areeda & Herbert Hovenkamp, Antitrust Law: An Analysis of Antitrust
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Forest moves to preclude Direct Purchaser Plaintiffs ("DPPs") from presenting evidence and argument regarding speculative "less restrictive alternatives."

In 2010, Forest and Mylan entered into an agreement to amend their distribution and supply agreement for authorized generic Lexapro. The 2010 Lexapro Amendment transferred to Mylan the obligation to manufacture the Lexapro authorized generic, which Forest expected would result in manufacturing cost savings and tens of millions of dollars in Medicaid rebate savings. The Lexapro Amendment also extended the minimum term of the agreement from one year to two years, which Forest projected would lead to profits in the second year of the authorized generic's sale.

DPPs apparently intend for their experts to opine that there were less restrictive alternatives by which Forest could have achieved the benefits that resulted from the Lexapro Amendment, notwithstanding that DPPs have offered neither support nor expert analysis to demonstrate the feasibility of these alternatives in terms of cost, overcoming existing contractual obligations, timing, and the myriad of other considerations involved in implementing these purported alternatives. While the law is clear that DPPs have the burden to prove that there were "*viable*" less restrictive alternatives to the Lexapro Agreement under the third step of the "rule of reason" analysis, DPPs' experts have offered no factual support or analysis to show that any of the alternatives they suggest were indeed viable options. *N. Am. Soccer League, LLC v. United States Soccer Fed'n, Inc.*, 883 F.3d 32, 45 (2d Cir. 2018) (declining to credit less restrictive alternatives that plaintiffs did not establish were of "equivalent viability" to challenged conduct); *O'Bannon v. NCAA,* 802 F.3d 1049, 1074 (9th Cir. 2015) (noting that the third step of the Rule of Reason analysis considers whether there are "viable," "substantially less restrictive alternatives" to challenged conduct); *Cty. of Tuolumne v. Sonora Cmty. Hosp.*, 236 F.3d 1148, 1159–60 (9th Cir.

2001) (holding that plaintiffs "failed to meet their burden of advancing *viable* less restrictive alternatives" where they "adduced virtually no evidence to show that their proposed alternatives are as effective as and, at the same time, not significantly more costly than" the challenged conduct) (emphasis added). Rather, DPPs merely speculate that Forest could have (1) entered an alternative agreement with a hypothetical, unspecified manufacturer that used "in house" and "lower priced" active pharmaceutical ingredient, (2) entered an alternative agreement with an unspecified manufacturer who Forest could have paid less and (3) waited to see if Mylan terminated the agreement after one year and either launched its own authorized generic product or entered an agreement with another unidentified manufacturer to produce the authorized generic in year two. *See e.g.*, Ex. 1, Expert Report of James Bruno ("Bruno Rep") at ¶ 78; Ex. 2, Reply Expert Report of James Bruno ("Bruno Reply Rep.") at ¶¶ 16, 27; Ex. 3, Reply Expert Report of Einer Elhauge ("Elhauge Reply Rep.") at ¶ 20. However, DPPs' experts have *no factual support* and have done *no analysis* to determine the cost of these supposed alternative agreements, or whether these supposed less restrictive alternatives were options that Forest actually could have pursued in a but-for world.

Instead, DPPs expect that the jury will believe that, because their experts say that these alternatives would have been feasible, less costly, and as effective, it must be so. Such *ipse dixit* expert opinion is plainly improper and should not be considered by the jury. *GE v. Joiner*, 522 U.S. 136, 146 (1997) (finding that nothing requires a district court to "admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert."); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 157 (1999) (same).

ARGUMENT

DPPs' experts speculate that there are alternative business arrangements that Forest could have made to accomplish the legitimate objectives Forest achieved through the Lexapro

Amendment. *See* Ex. 1, Bruno Rep. at ¶ 78; Ex. 2, Bruno Reply Rep at ¶¶ 16, 27; Ex. 3, Elhauge Reply Rep. at ¶ 20.

As this Court has already set forth, the rule of reason employs a three-part burden shifting framework that requires DPPs to prove, in step three, that the legitimate competitive effects that Forest achieved through the Lexapro Amendment could have been achieved through less restrictive means. *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC*, No. 15-cv-06549-CM (RWL), 2016 U.S. Dist. LEXIS 128349, *43 (S.D.N.Y. Sept. 13, 2016) (McMahon, J.). However, DPPs "cannot be permitted to offer possible less restrictive alternatives whose efficacy is mainly a matter of speculation" because "[a] skilled lawyer would have little difficulty imagining possible less restrictive alternative[s] . . . ." Philip Areeda & Herbert Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application ¶ 1913b (2017). Rather, the jury should hear evidence only of "viable" alternatives, or alternatives that are "virtually as effective in serving the legitimate objective without significantly increased cost." *See Tuolumne*, 236 F.3d at 1159–1160; *see also Soccer*, 883 F.3d 32, 45 (2d Cir. 2018) ("antitrust plaintiffs cannot just point to . . . less restrictive alternatives without additionally showing the *equivalent viability* of the alternatives proffered.") (emphasis added). Because DPPs' experts have not made any effort to analyze the specifics of each alternative, whether the alternatives were possible, or what the cost would be, they should not be permitted to testify about them.

I. "Less Restrictive Alternatives" Without Any Evidence of Viability May Not Be Presented to the Jury

Each of the "alternatives" offered by DPPs are devoid of support or analysis that even suggest that they were viable. Rather, DPPs apparently expect that the jury will simply trust that the less restrictive alternatives their experts imagine were feasible, cheaper options. However, this is precisely the type of speculative "less restrictive alternative" evidence that cannot be credited

against Forest's procompetitive justifications. *See Soccer*, 883 F.3d at 45; *O'Bannon v. NCAA*, 802 F.3d 1049, 1074 (9th Cir. 2015) (requiring plaintiffs "to make a strong evidentiary showing that its alternatives are viable"); *Tuolumne*, 236 F.3d at 1159 (stating that plaintiffs must show that a less restrictive alternative is "virtually as effective in serving the legitimate objective without significantly increased cost."); *United States v. Brown Univ.*, 5 F.3d 658, 679 (3d Cir. 1993) (finding that the plaintiff "bears the burden of proving that there exists a viable less restrictive alternative"). Indeed, without a robust analysis of the less restrictive alternatives that DPPs' experts proffer, the jury is left with no tools to appropriately evaluate whether the proposed alternatives are even less restrictive of competition. *Soccer*, 883 F.3d at 45 ("Less restrictive alternatives are those that would be less prejudicial to competition as a whole.") (internal quotation marks omitted). Tellingly, Mr. Bruno and Prof. Elhauge have done no analysis whatsoever of the competitive effects associated with their barebones alternatives:

Purported Less Restrictive Alternative to Achieving Manufacturing Cost Savings. DPPs' expert Mr. Bruno opines that Forest did not have to shift manufacturing responsibility to Mylan because there were other unspecified generic manufacturers that could have helped Forest achieve manufacturing cost savings by using in-house, lower priced active pharmaceutical ingredient ("API"). Ex. 1, Bruno Rep. at ¶ 78 (citing to no document or testimony regarding other generics' API cost, only to Forest's assessment of *Mylan's* cost of goods). However, Mr. Bruno did not provide a single example of a generic company who could have provided generic Lexapro API at a lower cost to Forest, or assess what the cost of this would have been. Ex. 4, Bruno Dep. 385:23–387:1 (noting that he did not ask for price quotes from other API manufacturers).

Mylan is a world-class manufacturer – one of the largest in the world. Mr. Bruno acknowledges that the reason that Mylan could not use its own internal API was that the particle

size was too small and the API could not be properly blended. Ex. 1, Bruno Rep. at ¶ 78. Nevertheless, Mr. Bruno did not investigate whether other generic manufacturers were producing API of an appropriate particle size. Ex. 4, Bruno Dep. at 388:1–388:25 (admitting that he did not investigate whether another API manufacturer was producing Lexapro API of an appropriate particle size that could have been properly blended under Forest's NDA). Further, Mr. Bruno did not consider Forest's existing contractual commitments to Mylan with respect to the Lexapro AG, and to Lundbeck (Forest's API supplier for Lexapro), including how those agreements would have to be amended and the time and cost of doing so.

Purported Less Restrictive Alternative to Achieving Medicaid Rebate Savings. Mr. Bruno further opines with absolutely no supporting analysis that Forest could have achieved the same Medicaid savings if it entered a deal with a manufacturer other than Mylan, "whom they could have paid far less." Ex. 2, Bruno Reply Rep. at ¶¶ 26, 27 (citing to no documents or testimony). However, Mr. Bruno (1) does not identify a single manufacturer who had capacity at the time, (2) does not identify a generic manufacturer with Mylan's scale, (3) does not assess what the cost of this alternative agreement would have been, and (4) does not consider how Forest could have avoided its contractual commitment to produce and supply Mylan with the authorized generic Lexapro product.

Purported Less Restrictive Alternatives to Achieving Second Year Profits. In the same conclusory fashion, Mr. Bruno opines that Forest "would have likely contracted with a different generic manufacturer to continue supplying the Authorized Generic" if Mylan terminated the Original Lexapro Agreement after year one. Ex. 2, Bruno Reply Rep. at ¶ 16 (citing to no documents or testimony in support of opinions). Similarly, DPPs' economic expert, Einer Elhauge, opines that instead of amending the minimum term of the Original Lexapro Agreement,

Forest could have waited to see if Mylan terminated the agreement after one year. Ex. 3, Elhauge Reply Rep. at ¶ 20 (citing to no documents or testimony in support of opinions). If Mylan did elect to terminate, Professor Elhauge opines that Forest could have launched its own authorized generic product or engaged another firm to sell Lexapro as an authorized generic. Ex. 2, Bruno Reply Rep. at ¶ 16; Ex. 3, Elhauge Reply Rep. at ¶ 20.

Neither Mr. Bruno nor Professor Elhauge assess what the cost of these alternatives would have been. Furthermore, both experts fail to identify a single generic company that could have obtained regulatory approval to manufacture an authorized generic product under Forest's NDA, or that would have been motivated (a year after other companies launched their generic Lexapro products) to undergo the expensive technology transfer that would have been required to take over manufacturing. *See* Ex. 2, Bruno Reply Rep. at ¶ 16; Ex. 3, Elhauge Reply Rep. at ¶ 20. They further fail to explain how this hypothetical generic company could have accomplished these steps in the short time between Mylan's notice of termination and the expiration of the agreement. *See* Ex. 4, Bruno Dep. 436:2–20 (agreeing that it would have taken two years for a company to become qualified to manufacture under Forest's NDA).

* * * * *

Thus, each of these "alternatives" is the kind of naked, speculative opinion that courts routinely discredit and fall far short of establishing the "equivalent viability" required by the Second Circuit. *See, e.g.*, *Soccer*, 883 F.3d at 45 (declining to credit less restrictive alternatives where no showing of "equivalent viability" was made); *Tuolumne*, 236 F.3d at 1159–1160 (finding plaintiffs failed to meet their burden of advancing viable less restrictive alternatives where they "adduced virtually no evidence" of viability); *see also Kumho*, 526 U.S. 137, 157 (holding that the

Federal Rules of Evidence do not "require[] a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.").

Moreover, any minimal probative value of DPPs' experts' speculative less restrictive alternatives is substantially outweighed by the prejudice that Forest will face if DPPs' experts are permitted to present their unsupported opinion testimony. Fed. R. Evid. 403. DPPs' experts have simply not done the analysis that is necessary to show that these less restrictive alternatives were feasible for Forest or that the alternatives would not have cost more than the Lexapro Amendment. Thus, DPPs experts should not be permitted to present these alternatives to the jury.

Instead, this Court should exercise its "gatekeeping" role and exclude this testimony. *Nimely v. City of N.Y.*, 414 F.3d 381, 396 (2d Cir. 2005). If the jurors hear the conclusory opinions that Mr. Bruno and Prof. Elhauge presented in their reports, they may be inclined to consider that they were legitimate options due entirely to the weight of the experts' experience, and not the legitimacy of their analysis. *Kumho*, 526 U.S. 137, 157 (holding that the Federal Rules of Evidence do not "require[] a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert."); *Nimely*, 414 F.3d at 397 (2d Cir. 2005) (finding that expert testimony is subject to Rule 403 and "the Supreme Court, echoed by members of our own court, has noted the uniquely important role that Rule 403 has to play in a district court's scrutiny of expert testimony, given the unique weight such evidence may have in a jury's deliberations."). Forest would be unfairly prejudiced by such testimony and could not unring the bell during cross-examination. *See United States Bank Nat'l Ass'n v. PHL Variable Life Ins. Co.*, 112 F. Supp. 3d 122, 134 (S.D.N.Y. 2015) (noting that expert testimony must be excluded when it is "so fundamentally unsupported that it can offer no assistance to the jury") (McMahon, J.); *Celebrity Cruises, Inc. v. Essef Corp.*, 434 F. Supp. 2d 169, 176, 179 (S.D.N.Y. 2006) (recognizing that

cross-examination can serve as a means to attack "shaky" expert opinion that is ultimately *admissible* and finding that expert testimony was inadmissible where there was "no evidence to support [expert's] speculation.") (emphasis added).

CONCLUSION

For the foregoing reasons, Forest respectfully requests that the Court grant its motion *in limine* to preclude evidence and argument of speculative less restrictive alternatives to (1) to achieving manufacturing cost savings, (2) to achieving Medicaid rebate savings, and (3) to achieving second year profits.

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Respectfully submitted,

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